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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,211	10/23/2001	Arnold W. Fogel	B30-050	2238

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,211	FOGEL, ARNOLD W.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE f this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendments filed December 2, 2002 have been entered.

The outstanding rejections of claims 8 ~~and~~ –36 are withdrawn in view of the amendments filed December 2, 2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "an emulsion exhibiting storage stability" in claims 8 and 25 renders the claims indefinite because it is not clear what the term "storage stability" refers to. It is known that stability is usually expressed or determined the percentage degraded under a specific condition such as certain temperature, pressure, etc. for example, is 95% degraded considered stable? How about 60%? Is it considered stable? Moreover, without expressly recite the specific conditions, one of ordinary skill in the art would not know what the term encompasses even though the percentage degraded is recited. For example, at room temperature, for 3 months, only 95% of the content is degraded. But the very same composition may have a different rate of degradation at a different conditions, for example, at 45°C, for 1 month, 65% of the content is degraded. Is the emulsion composition considered storage stable in the latter case?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogel (US Patent 6,126,949 from the IDS received June 11, 2002), Herstein (US Patent 5,902,591), and McCutcheon (McCutcheon's Emusifiers & Detergents North American Edition, 2000, 2000, page 18), references of record.

Fogel teaches the instant component A, a dialkyl fumarate, especially dibehenyl fumarate, is useful in harden or stiffen any cosmetically acceptable oil or water-in-oil emulsions and to enhance the stability of water-in-oil emulsion (See particularly the abstract). Fogel also teaches the emollients may be used with dibehenyl fumarate as petrolatum, mineral oil, various vegetable oils such as sunflower oil and safflower oil, and neopentanoates such as octyl dodecyl neopentanoate (See col. 3, line 65 - col. 4, line 59; also col. 10, line 64 in example 5). Fogel also teaches that the water-in-oil

emulsion may contain 20-25% to 55-60% of water and 40-45% to 75-80% of emollient oil (See col. 5, line 31-33). Fogel also teaches that nonionic emulsifiers may be used in the water-in-oil emulsion (See col. 6, line 25).

Herstein teaches that a 5-10% of vitamin C containing topical cosmetic composition employing several preferred emulsifiers: one of which is stearic monoethanolamide (the instant preferred component C) (See the abstract and also col. 5, line 23).

McCutcheon teaches the Arlacel P135, the instant preferred component B, is useful as an emulsifier for cosmetic use (See page 18, col. 2).

The references do not expressly teach the three components can be incorporated into a single composition. The references do not expressly teach the specific weight ratio of the three components as 1-15% of component A, 1-15% of component B; and the ratio among components A, B, and C as 1:1:1: or 3:2:3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the three components herein into a single composition in the weight ratio herein.

One of ordinary skill in the art would have been motivated to incorporate the three components herein into a single composition in the weight ratio herein because component B and C are known, based on the cited prior art, to be useful as emulsifiers in water-in-oil emulsion. Combining two agents, which are known to be useful as emulsifiers individually into a single composition useful for formulating an emulsion composition, is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069. Moreover,

dibehenyl fumarate, component A, is known to be useful to enhance the stability of water-in-oil emulsion. Therefore, further incorporating component A into the emulsion composition containing component B and C would have been reasonably expected to be useful in stabilizing the resulting emulsion composition. In addition, the optimization of result effect parameters (e.g., weight ratio or amount of the components) is obvious as being within the skill of the artisan, absent evidence to the contrary. No such evidence is seen herein.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, no data was set forth in the specification for demonstrating the unexpected result. Therefore, no unexpected results are seen herein.

Response to Arguments

Applicant's rebuttal arguments filed December 2, 2002 averring the specific ratio of the herein claimed components have been fully considered but they are not persuasive. Absent showing the criticality of the specific ratio and the specific components, possessing the teachings of the cited prior art, one of ordinary skill in the

art would incorporating the herein claimed components herein to form the herein claimed emulsion composition. Since these components are well known in the art to be emulsifier and stabilizer, the selection of one or another old and well known agents would be seen as a simple selection from among obvious alternatives, absent evidence to the contrary.

Applicant's rebuttal arguments filed December 2, 2002 averring McCutcheon not teaching Arlacel P135 as PEG 1500 dihydroxystearate have been considered, but are not found persuasive. Arlacel P135 is well known as PEG 1500 dihydroxystearate, as well as, an exemplified example set forth in the instant specification page 1, first paragraph. Please note that Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Since McCutcheon teaches Arlacel P135 as an emulsifier useful in cosmetics, one of ordinary skill in the art would incorporate such well known components into the composition herein claimed to form the herein claimed emulsion, absent evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 25, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

3/9/03